IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	MDL NO. 3094 THIS DOCUMENT RELATES TO ALL CASES JUDGE KAREN SPENCER MARSTON
THOMAS SHELTON, *Plaintiff,* v. ELI LILLY AND COMPANY., *Defendant.*	COMPLAINT AND JURY DEMAND CIVIL ACTION NO.:

COMPLAINT AND JURY DEMAND

Plaintiff files this Complaint pursuant to the Direct Filing Order and is to be bound by the rights, protections and privileges, and obligations of that Direct Filing Order and other Orders of the Court. Further, in accordance with the Direct Filing Order, Plaintiff hereby designates the United States District Court for the Middle District of Tennessee as Plaintiff's designated venue ("Original Venue"). Plaintiff makes this selection based upon one (or more) of the following factors (check the appropriate box(es)):

_X_ Plaintiff currently resides in Southside, Tennessee.

_X_ Plaintiff purchased and used Defendant(s)' products in Southside, Tennessee and Clarksville, Tennessee.

__The Original Venue is a judicial district in which Defendant _____ resides, and all Defendants are residents of the State in which the district is located (28 USC § 1391(b)(1)).

_X_ The Original Venue is a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, specifically (28 USC § 1391(b)(2)):
Use of Defendant's products in Montgomery County, Tennessee.

__ There is no district in which an action may otherwise be brought under 28 USC § 1391, and the Original Venue is a judicial district in which Defendant _____ is subject to the Court's personal jurisdiction with respect to this action (28 USC § 1391(b)(3)).

__ Other reason (please explain): _____.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides, which is Tennessee.

2. This Court has personal jurisdiction over Defendants consistent with the United States Constitution, Tenn. Code Ann. § 20-2-214, and Tenn. Code Ann. § 20-2-223 (Tennessee's "long-arm" statutes), as Plaintiff's claims arise out of Defendants' transaction of business and the tortious acts within the State of Tennessee, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of Tennessee unrelated to Plaintiff's claims.

NATURE OF THE CASE

3. This is an action for damages suffered by Plaintiff, Thomas Shelton, who was severely injured as a result of Plaintiff's use of Trulicity, an injectable prescription medication that is used to control blood sugar in adults with type 2 diabetes.

4. Trulicity is also known as dulaglutide. Trulicity works by targeting the body's receptors for GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1).

5. Trulicity belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

6. Defendants acknowledge that gastrointestinal events are well known side effects of the GLP-1RA class of drugs.[1] However, Defendants have downplayed the severity of the gastrointestinal events caused by their GLP-1RAs, never, for example, warning of the risk of gastroparesis ("paralyzed stomach") and its sequalae.

[1] See, e.g., CT Jones, Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell", Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight-loss-side-effects-1234794601 (visited on 9/26/23).

7. Gastroparesis is a condition that affects normal muscle movement in the stomach. Ordinarily, strong muscular contractions propel food through the digestive tract. However, in a person suffering from gastroparesis, the stomach's motility is slowed down or does not work at all, preventing the stomach from emptying properly. Gastroparesis can interfere with normal digestion and cause nausea, vomiting (including vomiting of undigested food), abdominal pain, abdominal bloating, severe dehydration, a feeling of fullness after eating just a few bites, undigested food hardening and remaining in the stomach, acid reflux, changes in blood sugar levels, lack of appetite, weight loss, malnutrition, and a decreased quality of life. There is no cure for gastroparesis.[2]

PARTY PLAINTIFF

8. Plaintiff, Thomas Shelton, is a citizen of the United States, and is a resident of the State of Tennessee.

9. Plaintiff was born on August 15, 1967.

10. For a substantial period of time, Plaintiff used Trulicity.

11. Plaintiff's physician(s) ("prescribing physician(s)") prescribed the Trulicity that Plaintiff used.

12. After using Trulicity, Plaintiff began to suffer from nausea, vomiting, and intractable abdominal pain. Plaintiff was diagnosed with gastroparesis.

13. As a result of using Defendant's Trulicity, Plaintiff was caused to suffer from gastroparesis and its sequelae, and as a result, sustained severe and permanent personal injuries, pain, suffering, and emotional distress, and incurred medical expenses.

PARTY DEFENDANTS

14. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation with a

[2] Gastroparesis, Mayo Clinic (June 11, 2022), available at https://www.mayoclinic.org/diseases-conditions/gastroparesis/symptoms-causes/syc-20355787 (visited on 9/26/23).

principal place of business at 893 S. Delaware St., Indianapolis, Indiana.

15. Eli Lilly designed, researched, manufactured, tested, labeled, advertised, promoted, marketed, sold, and/or distributed Trulicity and is identified on its label.[3]

FACTUAL BACKGROUND

A. FDA's Approval of Trulicity

16. On April 19, 2019, Eli Lilly submitted supplemental BLA 125469/S-033, requesting approval to expand its marketing of Trulicity by adding an indication for reduction of major cardiovascular events in adults with type 2 diabetes. On February 21, 2020, the FDA approved the request.[4]

17. On November 4, 2019, Eli Lilly submitted BLA 125469/S-036, seeking approval for higher doses (3 mg per week and 4.5 per week) of Trulicity. On September 3, 2020, the FDA approved that request.[5]

18. On May 17, 2022, Eli Lilly submitted BLA 125469/S-051, seeking to add an indication for a new patient population: "pediatric patients 10 years of age and older with type 2 diabetes mellitus." On November 17, 2022, the FDA approved the drug for pediatric use.[6]

19. At all times, Trulicity's label has indicated that Trulicity delays gastric emptying and that the delay in gastric emptying "diminishes with subsequent doses." However, Trulicity's label has never warned that Trulicity can cause gastroparesis or bowel obstruction and its sequelae.

B. Eli Lilly's Marketing and Promotion of Trulicity

[3] Trulicity prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=463050bd-2b1c-40f5-b3c3-0a04bb433309 (last visited on 10/30/2).

[4] FDA Approval Letter for BLA 125469/S-033 (Feb. 21, 2020), available https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/125469Orig1s033ltr.pdf (last visited Nov. 8, 2023 .

[5] *See News Release: FDA approves additional doses of Trulicity (dulaglutide) for the treatment of type 2 diabetes,* Eli Lilly (Sept. 3, 2020) available at https://investor.lilly.com/news-releases/news-release-details/fda-approves-additional-doses-trulicityr-dulaglutide-treatment (last visited Nov.15, 2023).

[6] FDA Approval Letter for BLA 125469/S-051 (Nov. 17, 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125469Orig1s051ltr.pdf (last visited Nov. 15, 2023).

20. Trulicity has been the top earning product for Eli Lilly for the past several years, with the drug bringing in more than $5.6 billion in revenue in 2022 in the United States alone. The demand for Trulicity is largely driven by Eli Lilly's advertising, which costs the company more than $1 billion annually. Indeed, Eli Lilly advertises Trulicity through its websites, press releases, in-person presentations, the drug's label, print materials, social media, and other public outlets. Eli Lilly's advertisements tout the health benefits of Trulicity, without warning of the risk of gastroparesis or its sequelae.[7]

21. Upon approval of Trulicity on September 18, 2014, an Eli Lilly spokesperson indicated that Trulicity "has demonstrated proven glycemic control, only has to be taken once weekly, and comes in an easy-to-use pen."[8] Although a press release accompanying Trulicity's approval acknowledged that "nausea," "vomiting" abdominal pain" were among the most common adverse reactions reported with use of Trulicity, the press release did not indicate that those common adverse reactions were symptoms of gastroparesis or warn of the risk of gastroparesis or its sequelae. Instead, the press release merely indicated that "Trulicity has not been studied in patients with ... [pre-existing] gastroparesis." [9]

22. Following the FDA's approval of Trulicity in September 2014, Eli Lilly launched its direct-to-consumer ad campaign in 2015, with print and digital ads first appearing in September 2015 and the first Trulicity television ad launching on October 19, 2015. [10]

---

[7] Eli Lilly and Company 2022 Annual Report, available at https://investor.lilly.com/static-files/2f9b7bb1-f955-448d-baa2-c4343d39ee62 (last visited Nov. 15, 2023).

[8] *Lilly's Trulicity (dulaglutide) Now Available in U.S. Pharmacies,* PR Newswire (Nov. 10, 2014), available at https://www.prnewswire.com/news-releases/lillys-trulicity-dulaglutide-now-available-in-us-pharmacies- 282138401.html (last visited Nov. 15, 2023).

[9] *News Release: FDA Approves Trulicity (dulaglutide), Lilly's Once-Weekly Therapy for Adults with Type 2 Diabetes,* Eli Lilly (Sept. 18, 2014), available at https://investor.lilly.com/news-releases/news-release-details/fda- approves-trulicitytm-dulaglutide-lillys-once-weekly-therapy (last visited Nov. 15, 2023).

[10] Beth Snyder Bulik, *One year after FDA nod, Eli Lilly's Trulicity launches first consumer campaign,* Fierce Pharma (Oct. 19, 2015) https://www.fiercepharma.com/dtc-advertising/one-year-after-fda-nod-eli-lilly-s-trulicity-launches-first-consumer-campaign (last visited Nov. 15, 2023).

23. On November 5, 2018, in a press release announcing Trulicity's "superiority in reduction of cardiovascular events," as shown by an internal clinical trial, Eli Lilly acknowledged that "[t]he safety profile of Trulicity ... was generally consistent with the GLP-1 receptor agonist class." Although the press release included a section titled "Important Safety Information for Trulicity," the press release did not warn that Trulicity can cause gastroparesis or its sequelae.[11]

24. In a February 21, 2020, press release announcing Trulicity's new indication for reduction of cardiovascular risk, Eli Lilly touted Trulicity's ability to reduce the risk of major adverse cardiovascular events, including heart attack and stroke, even in adults without established cardiovascular disease.[12] In the press release, Eli Lilly again indicated that "Trulicity's safety profile [is] consistent with the GLP-1 receptor agonist (RA) class," but despite warning of certain risks, the press release did not warn of the risk of gastroparesis, or its sequelae, associated with GLP-1RAs.

25. When announcing the approval of higher weekly doses of Trulicity in September 2020, Eli Lilly's press release indicated that "with the 3.0 and 4.5 [mg] doses available, people with type 2 diabetes who use Trulicity can benefit from additional A1C and weight loss as their condition progresses."[13] Despite touting the off-label use of Trulicity for "weight loss," Eli Lilly did not warn of the associated risk of gastroparesis or bowel obstruction and its sequelae.

26. In a similar January 2022 television ad featuring Olympic figure skater Madison

---

[11] *News Release: Trulicity (dulaglutide) demonstrates superiority in reduction of cardiovascular events for broad range of people with type 2 diabetes,* Eli Lilly (Nov. 5, 2018), available at https://investor.lilly.com/news- releases/news-release-details/trulicityr-dulaglutide-demonstrates-superiority-reduction (last visited Nov. 15, 2023).

[12] *News Release: Trulicity (dulaglutide) is the first and only type 2 diabetes medicine approved to reduce cardiovascular events in adults with and without established cardiovascular disease,* Eli Lilly (Feb. 21, 2020), available at https://investor.lilly.com/news-releases/news-release-details/trulicityr-dulaglutide-first-and-only-type-2-diabetes-medicine (last visited Nov. 15, 2023).

[13] *See* Trulicity TV advertisement, available at https://www.youtube.com/watch?v=eVA1vYV980w (last visited Nov. 15, 2023); Beth Snyder Bulik, *Lilly warms up for Olympics with Team USA athletes in ads for Trulicity, Emgality and Verzenio,* Fierce Pharma (July 7, 2021), available at https://www.fiercepharma.com/marketing/lilly- warms-up-for-olympics-team-usa-athletes-ads-for-trulicity-emgality-and-verzenio (last visited Nov. 15, 2023).

Chock and her mother, Eli Lilly again indicated that Trulicity was the "right choice" for people with type 2 diabetes. However, the ad did not warn that Trulicity can cause gastroparesis or bowel obstruction and its sequelae.[14]

27. In January 2022, the FDA determined that Eli Lilly's "10,800 Minutes" Instagram advertisement for Trulicity "ma[de] false or misleading claims and representations about the benefits and risks of Trulicity" and that the ad elicits "a misleading impression regarding the safety and effectiveness of Trulicity" that "minimizes the risks associated with the use of Trulicity." In response to a letter from the FDA, Eli Lilly temporarily removed the Trulicity Instagram account ."[15] The FDA citation is emblematic of Eli Lilly's willingness to mislead and omit important information, focusing on profit over safety, specifically with respect to Trulicity.

28. That same month, it was reported that Trulicity was the most advertised drug on United States television, with Eli Lilly spending an estimated $36.2 million on national television advertisements in January 2022 alone.[16]

29. In another Trulicity television ad that premiered in February 2022, Eli Lilly boasted that Trulicity "can help you lose up to ten pounds," a use for which Trulicity is not indicated, but did not mention the risk of gastroparesis or bowel obstruction and its sequelae.[17].

30. Similarity, Eli Lilly's website used to promote Trulicity (Trulicity.com) states that people taking Trulicity "lost up to 10 lbs," without disclosing the risk of gastroparesis or bowel

[14] *See* Trulicity TV advertisement (Madison Chock), available at https://www.ispot.tv/ad/q3ii/trulicity-shes-got-this-featuring-madison-chock (last visited Nov. 15, 2023).
[15] Fraiser Kansteiner, *FDA chides Eli Lilly for 2nd misleading ad in 2 months, this time for diabetes blockbuster Trulicity,* Fierce Pharma (Jan. 25, 2022), available at https://www.fiercepharma.com/marketing/fda-chides-lilly-for-second-misleading-ad-2-months-time-for-diabetes-med-trulicity (last visited Nov. 15, 2023).
[16]Ben Adams, *Eli Lilly's Trulicity dethrones Dupixent, taking January's TV ad spending crown,* Fierce Pharma (Feb. 4, 2022), available at https://www.fiercepharma.com/marketing/sanofi-regeneron-s-dupixent-de-throned-as-lilly-s-trulicity-takes-crown-january-s-biggest (last visited Nov. 15, 2023).

[17] Trulicity TV advertisement ("Father-Son"), available at https://www.ispot.tv/ad/q4Kl/trulicity-father-son (last visited Nov. 15, 2023).

obstruction.[18]

31. By the end of 2022, the market was experiencing shortages of Trulicity due to "high demand" driven by Eli Lilly's advertising.[19]

C. The Medical Literature and Clinical Trials Gave Defendants Notice of Gastroparesis Being Causally Associated with GLP-1RAs.

32. As previously noted, Trulicity (dulaglutide) belongs to a class of drugs called GLP-1 receptor agonists ("GLP-1RAs").

33. Medications within the GLP-1RA class of drugs mimic the activities of physiologic GLP-1, which is a gut hormone that activates the GLP-1 receptor in the pancreas to stimulate the release of insulin and suppress glucagon.[20]

34. Because the risk of gastroparesis is common to the entire class of drugs, any published literature regarding the association between gastroparesis and *any* GLP-1RA (such as tirzepatide, exenatide, liraglutide, albiglutide, dulaglutide, lixisenatide, and semaglutide) should have put Defendants on notice of the need to warn patients and prescribing physicians of the risk of gastroparesis associated with these drugs.

35. In addition to pancreatic effects, the published medical literature shows that GLP-1 slows gastric emptying. As early as 2010, a study published in The Journal of Clinical Endocrinology & Metabolism indicated this effect.[21]

36. Defendants knew or should have known of this risk of gastroparesis from the

[18] *See* https://www.trulicity.com/what-is-trulicity#what-is-trulicity..
[19] https://www.fiercepharma.com/manufacturing/after-novos-wegovy-supply-woes-lillys-would-be-obesity-rival-tirzepatide-runs-scarce
[20] 23 Hinnen D, Glucagon-Like Peptide 1 Receptor Agonists for Type 2 Diabetes, 30(3) Diabetes Spectr., 202–210 (August 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5556578/ (visited on 9/26/23).
[21] Deane AM et al., Endogenous Glucagon-Like Peptide-1 Slows Gastric Emptying in Healthy Subjects, Attenuating Postprandial Glycemia, 95(1) J Clinical Endo Metabolism, 225-221 (January 1, 2010), available at https://academic.oup.com/jcem/article/95/1/215/2835243 (visited on 9/26/23); American Society of Anesthesiologists, Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news- releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should-stop-before-elective- surgery (visited on 9/26/23).

clinical trials, medical literature, and case reports.

37. A 2016 trial funded by Novo Nordisk measuring semaglutide and cardiovascular outcomes in patients with type 2 diabetes found more gastrointestinal disorders in the semaglutide group than in the placebo group, including a severe adverse event report of impaired gastric emptying with semaglutide 0.5 mg together with other serious gastrointestinal adverse events such as abdominal pain (upper and lower), intestinal obstruction, change of bowel habits, vomiting, and diarrhea.[22]

38. Two subjects in a semaglutide trial pool by Novo Nordisk reported moderate adverse events of impaired gastric emptying and both subjects permanently discontinued treatment due to the adverse events. Three subjects also reported mild adverse events of impaired gastric emptying in the semaglutide run-in period of trial 4376.

39. A study published in 2017 evaluated the effect of GLP-1RAs on gastrointestinal tract motility and residue rates and explained that "GLP-1 suppresses gastric emptying by inhibiting peristalsis of the stomach while increasing tonic contraction of the pyloric region." The study authors concluded that the GLP-1RA drug liraglutide "exhibited gastric-emptying delaying effects" and "the drug also inhibited duodenal and small bowel movements at the same time."[23]

40. Another study in 2017 reviewed the survey results from 10,987 patients and 851 physicians and found that "GI-related issues were the top two patient-reported reasons for GLP-1RA discontinuation in the past 6 months, with 'Made me feel sick' as the most frequently reported reason (64.4%), followed by 'Made me throw up' (45.4%)."[24] As explained above, these are

[22] Marso, SP, et al., Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes, N. Eng. J. Med. 375:1834-1844 (November 2016), available at https://www.nejm.org/doi/10.1056/NEJMoa1607141 (visited on 10/19/23).
[23] Nakatani Y et al., Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy, 43(5) Diabetes & Metabolism, 430-37 (October 2017), available at https://www.sciencedirect.com/science/article/pii/S1262363617301076 (visited on 9/26/23).
[24] Sikirica M et al., Reasons for discontinuation of GLP1 receptor agonists: data from a real-world cross-sectional survey of physicians and their patients with type 2 diabetes, 10 Diabetes Metab. Syndr. Obes., 403-412 (September 2017), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5630073/

symptoms of gastroparesis.

41. A 2019 study of the GLP-1RA drug dulaglutide identified adverse events for impaired gastric emptying and diabetic gastroparesis.

42. In August of 2020, medical literature advised that some "patients do not know they have diabetic gastroparesis until they are put on a glucagon-like peptide 1 (GLP-1) receptor agonist such as ... semaglutide ... to manage their blood glucose." The article went on to explain that "[t]his class of drugs can exacerbate the symptoms of diabetic gastroparesis. ... Thus, GLP-1 receptor agonist therapy is not recommended for people who experience symptoms of gastroparesis."[25]

43. In a September 2020 article funded and reviewed by Novo Nordisk, scientists affiliated with Novo Nordisk reported on two global clinical trials that evaluated the effect of semaglutide in patients with cardiovascular events and diabetes. More patients permanently discontinued taking oral semaglutide (11.6%) than placebo (6.5%) due to adverse events. The most common adverse events associated with semaglutide were nausea (2.9% with semaglutide versus 0.5% with placebo), vomiting (1.5% with semaglutide versus 0.3% with placebo), and diarrhea (1.4% with semaglutide versus 0.4% with placebo). Injectable semaglutide had a discontinuation rate of 11.5-14.5% (versus 5.7-7.6% with placebo) over a two-year period. The authors acknowledged the potential for severe gastrointestinal events, warning that "[f]or patients reporting severe adverse gastrointestinal reactions, it is advised to monitor renal function when initiating or escalating doses of oral semaglutide." For patients with other comorbidities, the study warned that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs." The study further identified as one "key clinical take-home point" that "patients should be made aware of the occurrence of gastrointestinal adverse events with GLP-1RAs."[26]

[25] Young CF, Moussa M, Shubrook JH, Diabetic Gastroparesis: A Review, Diabetes Spectr. (2020), Aug; 33(3): 290–297, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7428659/ (visited on 9/26/23).
[26] Mosenzon O, Miller EM, & Warren ML, Oral semaglutide in patients with type 2 diabetes and cardiovascular disease, renal impairment, or other comorbidities, and in older patients, Postgraduate Medicine (2020), 132:sup2, 37-

44. A July 2021 article funded and reviewed by Novo Nordisk considered 23 randomized control trials conducted across the United States, Japan, and China and concluded that "gastrointestinal disturbances" were "well-known" side effects associated with semaglutide use. When compared with placebos, the subcutaneous (injection) form of the drug induced nausea in up to 20% of patients (versus up to 8% on the placebo group), vomiting in up to 11.5% of patients (versus up to 3% in the placebo group) and diarrhea in up to 11.3% of patients (versus up to 6% in the placebo group). Overall, the percentage of patients experiencing adverse events that led to trial product discontinuation was greatest for gastrointestinal related adverse events, with some trials experiencing 100% discontinuation due to gastrointestinal related adverse events. The mean value of gastrointestinal related adverse events that led to discontinuation averaged 57.75%. Semaglutide appears to be associated with more frequent vomiting and nausea as compared to other GLP-1RAs. The study acknowledges that while nausea and vomiting are unwanted side effects, "they may be partly responsible for aspects of the drug's efficacy[.]"[27]

45. An October 2021 article in the Journal of Investigative Medicine ("JIM") concluded that because gastroparesis can be associated with several medications, "[i]t is crucial to identify the causative drugs as discontinuation of the drug can result in resolution of the symptoms[.]" In diabetics, making this determination can be particularly "tricky" because both diabetes and GLP-1RAs can cause delayed gastric emptying. As such, "the timeline of drug initiation and symptom onset becomes of the upmost importance." The authors reviewed two case reports (discussed below) and concluded that history taking and making an accurate diagnosis of diabetic gastroparesis versus medication-induced gastroparesis is critical.[28]

47, available at https://doi.org/10.1080/00325481.2020.1800286 (visited on 9/26/23).

[27] Smits MM & Van Raalte DH (2021), Safety of Semaglutide, Front. Endocrinol., 07 July 2021, doi: 10.3389/fendo.2021.645563, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8294388/ (visited on 9/26/23).

[28] Kalas MA, Galura GM, McCallum RW, Medication-Induced Gastroparesis: A Case Report, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at

46. Case Report #1 in JIM involved a 52-year-old female with long-standing (10 years) well-controlled, type 2 diabetes who had been taking weekly semaglutide injections approximately one month prior to the onset of gastroparesis symptoms. The patient was referred with a 7-month history of post-prandial epigastric pain, accompanied by fullness, bloating, and nausea. A gastric emptying study showed a 24% retention of isotope in the patient's stomach at four hours, indicative of delayed gastric emptying. The patient discontinued semaglutide and her symptoms resolved after six weeks. The case report authors concluded that "thorough history taking revealed the cause [of gastroparesis] to be medication induced."[29]

47. Case Report #2 in JIM involved a 57-year-old female with a long-standing (16 years) type 2 diabetes who had been taking weekly dulaglutide injections (another GLP-1RA) for 15 months and suffering from abdominal bloating, nausea, and vomiting for 12 of those months. A gastric emptying study showed 35% retention of isotope in the patient's stomach at four hours, indicating delayed gastric emptying. After discontinuing dulaglutide, the patient experienced a gradual resolution of symptoms over a four-week period.[30]

48. A June 2022 study reported GLP-1RA Mounjaro (tirzepatide) adverse events of vomiting, nausea, and "severe or serious gastrointestinal events."[31]

49. An October 2022 study analyzed 5,442 GLP-1RA adverse gastrointestinal events. 32% were serious, including 40 deaths, 53 life-threatening conditions, and 772 hospitalizations. The primary events were nausea and vomiting. There were also adverse events for impaired gastric emptying.[32]

---

[29] Kalas MA, Galura GM, McCallum RW, Medication-Induced Gastroparesis: A Case Report, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).

[30] Kalas MA, Galura GM, McCallum RW, Medication-Induced Gastroparesis: A Case Report, J Investig Med High Impact Case Rep. 2021 Jan-Dec; 9: 23247096211051919, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8529310/ (visited on 9/26/23).

[31] Jastreboff, Tirzepatide Once Weekly for the Treatment of Obesity, N Engl J Med, at 214 (June 4, 2022) (https://doi.org/10.1056/nejmoa2206038).

[32] Shu, Gastrointestinal adverse events associated with semaglutide: A pharmacovigilance study based on FDA adverse

50. A January 2023 meta-analysis of GLP-1RA (Mounjaro) adverse events reported high rates of nausea and vomiting.[33]

51. In February 2023, a longitudinal study of GLP-1RA (dulaglutide) reported adverse events for nausea and vomiting, and one adverse event of impaired gastric emptying.[34]

52. On March 28, 2023, a case study concluded that impaired gastric emptying is "a significant safety concern, especially since it is consistent with the known mechanism of action of the drug."[35]

53. On June 29, 2023, the American Society of Anesthesiologists ("ASA") warned that patients taking semaglutide and other GLP-1RAs should stop the medication at least a week before elective surgery because these medications "delay gastric (stomach) emptying" and "the delay in stomach emptying could be associated with an increased risk of regurgitation and aspiration of food into the airways and lungs during general anesthesia and deep sedation." The ASA also warned that the risk is higher where patients on these medications have experienced nausea and vomiting.[36]

54. News sources have identified the potential for serious side effects in users of Ozempic, including gastroparesis, leading to hospitalization.[37] For example, NBC News reported

---

event reporting system, Front. Public Health (Oct. 20, 2022). (https://doi.org/10.3389%2Ffpubh.2022.996179).

[33] Mirsha, Adverse Events Related to Tirzepatide, J. of Endocrine Society (Jan. 26, 2023) (https://doi.org/10.1210%2Fjendso%2Fbvad016).

[34] Chin, Safety and effectiveness of dulaglutide 0.75 mg in Japanese patients with type 2 diabetes in real-world clinical practice: 36 month postmarketing observational study, J Diabetes Investig (Feb. 2023) (https://doi.org/10.1111%2Fjdi.13932).

[35] Klein, Semaglutide, delayed gastric emptying, and intraoperative pulmonary aspiration: a case report, Can J. Anesth (Mar. 28, 2023) (https://doi.org/10.1007/s12630-023-02440-3).

[36] American Society of Anesthesiologists, Patients Taking Popular Medications for Diabetes and Weight Loss Should Stop Before Elective Surgery, ASA Suggests (June 29, 2023), available at https://www.asahq.org/about-asa/newsroom/news-releases/2023/06/patients-taking-popular-medications-for-diabetes-and-weight-loss-should- stop-before-elective-surgery (visited on 9/26/23).

[37] Penny Min, Ozempic May Cause Potential Hospitalizations, healthnews (June 26, 2023), available at https://healthnews.com/news/ozempic-may-cause-potential-hospitalizations/ (last visited on 9/26/23); Elizabeth Laura Nelson, These Are the 5 Most Common Ozempic Side Effects, According to Doctors, Best Life (April 3, 2023), available at https://bestlifeonline.com/ozempic-side-effects-news/ (last visited on 9/26/23); Cara Shultz, Ozempic and Wegovy May Cause Stomach Paralysis in Some Patients, People (July 26, 2023), available at https://people.com/ozempic-wegovy-weight-loss-stomach-paralysis-7565833 (last visited on 9/26/23); CBS News Philadelphia, Popular weight loss drugs Ozempic and Wegovy may cause stomach paralysis, doctors warn (July 23,

in January 2023 that some Ozempic users were discontinuing use because their symptoms were unbearable, and one user said that five weeks into taking the medication she found herself unable to move off the bathroom floor because she had "vomited so much that [she] didn't have the energy to get up."[38] CNN reported in July that one Ozempic user diagnosed with gastroparesis vomits so frequently that she had to take a leave of absence from her teaching job.[39]

55. A July 25, 2023, article in Rolling Stone magazine—"*Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell*'"—highlighted three patients who have suffered severe gastrointestinal related events, including gastroparesis, as a result of their use of GLP-1RAs. Patient 1 (female, age 37) reported incidents of vomiting multiple times per day and being unable to eat. The patient's physician diagnosed her with severe gastroparesis and concluded that her problems were caused and/or exacerbated by her use of a GLP-1RA medication. Patient 2 (female) used Ozempic for one year and reported incidents of vomiting, including multiple times per day. The patient's physician diagnosed her with severe gastroparesis related to her Ozempic use. Patient 3 (female, age 42) experienced severe nausea both during and after she discontinued use of a GLP-1RA. In a statement to Rolling Stone, Novo Nordisk acknowledged that "[t]he most common adverse reactions, as with all GLP-1 RAs, are gastrointestinal related." Novo Nordisk further stated that while "GLP-1 RAs are known to cause a delay in gastric emptying, … [s]ymptoms of delayed gastric emptying, nausea and vomiting are listed as side effects." Novo Nordisk did not claim to have warned consumers about gastroparesis, or other severe gastrointestinal issues.[40]

2023), available at https://www.cbsnews.com/philadelphia/news/weight-loss-drugs-wegovy-ozempic-stomach-paralysis/ (last visited on 9/26/23).

[38] Bendix A, Lovelace B Jr., What it's like to take the blockbuster drugs Ozempic and Wegovy, from severe side effects to losing 50 pounds, NBC News (Jan. 29, 2023), available at https://www.nbcnews.com/health/health-news/ozempic-wegovy-diabetes-weight-loss-side-effects-rcna66493 (visited on 9/26/23).

[39] Brenda Goodman, They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed, CNN (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis/index.html (visited on 9/26/23).

[40] CT Jones, Ozempic Users Report Stomach Paralysis from Weight Loss Drug: 'So Much Hell", Rolling Stone (July 25, 2023), available at https://www.rollingstone.com/culture/culture-news/ozempic-stomach-paralysis-weight- loss-

56. On July 25, 2023, CNN Health reported that patients taking Ozempic have been diagnosed "with severe gastroparesis, or stomach paralysis, which their doctors think may have resulted from or been exacerbated by the medication they were taking, Ozempic." Another patient taking Wegovy (semaglutide) suffered ongoing nausea and vomiting, which was not diagnosed, but which needed to be managed with Zofran and prescription probiotics.[41]

57. On July 26, 2023, a New York hospital published an article to its online health blog section "What You Need to Know About Gastroparesis" entitled "Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines." It was reported that a growing number of gastroparesis cases had been seen in people taking GLP-1RAs. The article noted that the weight-loss drugs can delay or decrease the contraction of muscles that mix and propel contents in the gastrointestinal tract leading to delayed gastric emptying. One concern raised was that patients and doctors often assume the symptoms of gastroparesis are reflux or other gastrointestinal conditions, meaning it may take a long time for someone to be diagnosed correctly.[42]

58. In an October 5, 2023, Research Letter published in the Journal of the American Medical Association ("JAMA"), the authors examined gastrointestinal adverse events associated with GLP-1RAs used for weight loss in clinical setting and reported that use of GLP-1RAs compared with use of bupropion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.[43] The study found that patients prescribed GLP-1RAs were at 4.22 times higher risk of intestinal obstruction and at 3.67 times higher risk of gastroparesis.

---

side-effects-1234794601 (visited on 9/26/23).

[41] Brenca Goodman, They took blockbuster drugs for weight loss and diabetes. Now their stomachs are paralyzed, CNN Health (July 25, 2023), available at https://www.cnn.com/2023/07/25/health/weight-loss-diabetes-drugs-gastroparesis (last visited on 9/26/23).

[42] Delayed Stomach Emptying Can Be Result of Diabetes or New Weight-Loss Medicines, Montefiore Health Blog article (released July 26, 2023), available at https://www.montefiorenyack.org/health-blog/what-you-need-know-about-gastroparesis (last visited on 9/26/2023).

[43] Mohit Sodhi, et al., Risk of Gastrointestinal Adverse Events Associated with Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss, JAMA (published online October 5, 2023), available at https://jamanetwork.com/journals/jama/fullarticle/2810542 (last visited 10/19/23).

59. The medical literature listed above is not a comprehensive list, and several other case reports have indicated that GLP-1RAs can cause gastroparesis and impaired gastric emptying.[44]

60. Defendants knew or should have known of the causal association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, but they ignored the causal association. Defendants' actual and constructive knowledge derived from their clinical studies, case reports, medical literature, including the medical literature and case reports referenced above in this Complaint.

61. On information and belief, Defendants not only knew or should have known that their GLP-1RAs cause delayed gastric emptying, resulting in risks of gastroparesis, but they may have sought out the delayed gastric emptying effect due to its association with weight loss. For example, a recent study published in 2023 notes that "it has been previously proposed that long-acting GLP-1RAs could hypothetically contribute to reduced energy intake and weight loss by delaying GE [gastric emptying,]" and the study authors suggested "further exploration of peripheral mechanisms through which s.c. semaglutide, particularly at a dose of 2.4. mg/week, could potentially contribute to reduced food and energy intake."[45]

D. The Eli Lilly Defendants Failed to Warn of the Risk of Gastroparesis from Trulicity

62. The Prescribing Information for Trulicity (the "label") discloses "Warnings and Precautions" and "Adverse Reactions" but does not adequately warn of the risk of gastroparesis

[44] Cure, Exenatide and Rare Adverse Events, N. Eng. J. Med. (May 1, 2008) (https://doi.org/10.1056/nejmc0707137); Rai, Liraglutide-induced Acute Gastroparesis, Cureus (Dec. 28, 2018) (https://doi.org/10.7759%2Fcureus.3791); Guo, A Post Hoc Pooled Analysis of Two Randomized Trials, Diabetes Ther (2020) (https://doi.org/10.1007%2Fs13300-020-00869-z); Almustanyir, Gastroparesis With the Initiation of Liraglutide: A Case Report, Cureus (Nov. 28, 2020) (https://doi.org/10.7759/cureus.11735); Ishihara, Suspected Gastroparesis With Concurrent Gastroesophageal Reflux Disease Induced by Low-Dose Liraglutide, Cureus (Jul. 16, 2022) (https://doi.org/10.7759/cureus.26916); Preda, Gastroparesis with bezoar formation in patients treated with glucagon-like peptide-1 receptor agonists: potential relevance for bariatric and other gastric surgery, BJS Open (Feb. 2023) (https://doi.org/10.1093%2Fbjsopen%2Fzrac169).

[45] Jensterle M et al., Semaglutide delays 4-hour gastric emptying in women with polycystic ovary syndrome and obesity, 25(4) Diabetes Obes. Metab. 975-984 (April 2023), available at https://dom-pubs.onlinelibrary.wiley.com/doi/epdf/10.1111/dom.14944 (visited on 9/26/23).

and its sequalae.[46]

63. The Trulicity label lists nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain as common adverse reactions, but it does not indicate a severity of symptoms. Even though the label warns about the risk of Severe Gastrointestinal Disease, gastroparesis is not specifically mentioned.

64. Instead of properly disclosing gastrointestinal risks, the label for Trulicity encourages prescribing physicians and patients to ignore the signs of gastroparesis and continue therapy with Trulicity because the Drug Interactions and Clinical Pharmacology sections of the label state that the delayed gastric emptying caused by Trulicity "is largest after the first does and diminishes with subsequent doses. [47]

65. Similarly, Eli Lilly's main promotional website for Trulicity (trulicity.com) includes a variety of information about the benefits of Trulicity relating to blood sugar, cardiovascular health, and weight loss, and includes a section about "Side Effects" and a sidebar containing a "SAFETY SUMMARY WITH WARNINGS." However, Eli Lilly does not disclose the risk of gastroparesis within either the "Side Effects" or "SAFETY SUMMARY WITH WARNINGS" sections of the website. [48]

66. Nothing in the label for Trulicity has ever disclosed gastroparesis as a risk of taking Trulicity.

67. None of Defendant's additional advertising or promotional materials warned prescription providers or the general public of the risks of gastroparesis and its sequelae.

---

[46] Trulicity prescribing information, available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=463050bd-2b1c-40f5-b3c3-0a04bb433309 (last visited on 10/30/23)

[47] *See* Trulicity Label (revised Nov. 2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Nov. 15, 2023).

[48] *See* Trulicity.com (last visited Nov. 15, 2023).

68. Defendant knew or should have known of the casual association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequalae. Defendant's actual and constructive knowledge derived from its clinical studies, case reports, and the medical literature, including the medical literature and case reports referenced in this Complaint.

69. Upon information and belief, Defendant ignored the casual association between the use of GLP-1RAS and the risk of developing gastroparesis and its sequelae.

70. Eli Lilly's failure to disclose information that it processed regarding the casual association between the use of GLP-1RAs and the risk of developing gastroparesis and its sequelae, rendered the warnings for Trulicity inadequate.

71. Upon information and belief, as a result of Eli Lilly's inadequate warnings, the medical community at large, and Plaintiff's prescribing physician(s) in particular, were not aware that Trulicity can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the label might be sequalae of gastroparesis.

72. Upon information and belief, had Eli Lilly inadequate warnings, the medical community at large, and Plaintiff's prescribing physician(s) in particular, were not aware that Trulicity can cause gastroparesis, nor were they aware that "common adverse reactions" listed on the label might be sequelae of gastroparesis.

73. Upon information and belief, had Eli Lilly adequately warned Plaintiff's prescribing physician(s) that Trulicity is casually associated with gastroparesis and its sequalae, then the physician's prescribing decision would have been changed by not prescribing Trulicity when the symptoms first started.

74. By reason of the foregoing acts and omissions, Plaintiff was and still is caused to suffer from gastroparesis and its sequelae, which resulted in severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or

medications, and fear of developing any of the above-named health consequences.

FIRST CAUSE OF ACTION
(NEGLIGENCE – AGAINST ALL DEFENDANTS)

75. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

76. At all relevant times, the Eli Lilly Defendants, directly or indirectly, designed, researched, manufactured, tested, advertised, promoted, marketed, and/or distributed the Trulicity that was used by the Plaintiff.

77. At all relevant times, the Eli Lilly Defendants had a duty to exercise reasonable care in the manufacture, marketing, advertisement, supply, storage, transport, packaging, sale, and distribution of Trulicity products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that did not cause users to suffer from unreasonable, dangerous side effects without an adequate warning—when used alone or in foreseeable combination with other drugs. At all relevant times, the Eli Lilly Defendants knew, or in the exercise of reasonable care, should have known of the hazards and dangers associated with Trulicity and, specifically, that use of this drug could cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, Wernicke's encephalopathy, and death.

78. At all relevant times, the Eli Lilly Defendants knew, or in the exercise of reasonable care, should have known that the use of Trulicity could cause Plaintiff's injuries and, thus, created a dangerous and unreasonable risk of injury to Plaintiff and other users of this product for which the Eli Lilly Defendants did not warn.

79. The Eli Lilly Defendants knew or in the exercise of reasonable care should have known that users and consumers were unaware of the risks and magnitude of the risks associated with the use of Trulicity.

80. The Eli Lilly Defendants breached their duty of care to Plaintiff and Plaintiff's treating physicians, in the warning, testing, monitoring, and pharmacovigilance of Trulicity.

81. In disregard of its duties, the Eli Lilly Defendants committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, overpromoting, marketing, formulating, creating, developing, designing, selling, and distributing Trulicity without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, overpromoting, marketing, advertising, formulating, creating, developing, and distributing Trulicity and, upon information and belief, while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Trulicity.

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Trulicity were safe for its intended use;

d. Upon information and belief, failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that the Eli Lilly Defendants knew and had reason to know that Trulicity was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that Trulicity's risk of harm was unreasonable and that there were

safer and effective alternative products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Trulicity;

g. Advertising, marketing, and recommending the use of Trulicity while concealing and failing to disclose or warn of the dangers known by the Eli Lilly Defendants to be connected with and inherent in the use of Trulicity;

h. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Trulicity so as to avoid the risk of serious harm associated with the use of Trulicity. Failing to design and manufacture Trulicity so as to ensure the drug was at least as safe and effective as other similar products;

i. Failing to ensure that Trulicity was accompanied by proper and accurate warnings about the risk of severe gastrointestinal problems including gastroparesis and its sequalae;

j. Failing to ensure that Trulicity was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Trulicity and that use of Trulicity created a high risk of severe injuries; and

k. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Trulicity.

82. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

83. As a direct and proximate result of the Eli Lilly Defendants' negligent testing, monitoring, and pharmacovigilance of Trulicity , the Eli Lilly Defendants introduced a drug that they knew or should have known would cause serious and severe complications in people, including

Plaintiff, such as gastroparesis and Wernicke's encephalopathy, both incurable conditions, and Plaintiff has been injured catastrophically and sustained severe and permanent pain, suffering, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

84. The aforementioned negligence and wrongs done by the Eli Lilly Defendants were aggravated by the kind of grossly negligent conduct and disregard for the rights of others, the public, and Plaintiff, for which the law allows the imposition of exemplary or punitive damages, in that the Eli Lilly Defendants' conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and the Eli Lilly Defendants proceeded with a reckless disregard to the rights, safety, or welfare of others, including Plaintiff.

85. The Eli Lilly Defendants are liable in tort to Plaintiff for wrongful conduct.

86. As a direct and proximate result of one or more of the above-stated negligent acts by the Eli Lilly Defendants, Plaintiff suffered bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability, and punitive damages.

SECOND CAUSE OF ACTION
(NEGLIGENT FAILURE TO WARN – AGAINST ALL DEFENDANTS)

87. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

88. A duty is imposed on producers, manufacturers, distributors, lessors, and sellers of a product to exercise all reasonable care when producing, manufacturing, distributing, leasing, and selling their products.

89. At all relevant times, the Eli Lilly Defendants, directly or indirectly, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the

Trulicity that was used by the Plaintiff.

90. The Eli Lilly Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Trulicity into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis and its sequelae.

91. Trulicity was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Eli Lilly Defendants.

92. At all relevant times, and at the times Trulicity left the Eli Lilly Defendants' control, the Eli Lilly Defendants knew or should have known that Trulicity was and is unreasonably dangerous because the Eli Lilly Defendants did not adequately warn of the risks of severe gastrointestinal events and digestive events, especially when used in the form and manner as provided by the Eli Lilly Defendants.

93. Despite the fact that the Eli Lilly Defendants knew or should have known that Trulicity caused unreasonably dangerous injuries, the Eli Lilly Defendants continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

94. Despite the fact that the Trulicity Defendants knew or should have known that Trulicity caused unreasonably dangerous injuries, the Eli Lilly Defendants continued to market Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

95. The Eli Lilly Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury because of their failure to provide adequate warnings, as set forth herein.

96. At all relevant times, given its increased safety risks, Trulicity was not fit for the

ordinary purpose for which it was intended— namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

97. At all relevant times, given the increased safety risks, Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

98. The Eli Lilly Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Trulicity into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous injuries, such as severe gastrointestinal events, including gastroparesis and gastroenteritis and gallbladder removal.

99. At all relevant times, Plaintiff was using Trulicity for the purposes and in a manner normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

100. The Trulicity designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Eli Lilly Defendants were defective due to inadequate warnings or instructions, as the Eli Lilly Defendants knew or should have known that the products created a risk of serious and dangerous injuries, including severe gastrointestinal events (e.g., gastroparesis) and digestive events, as well as other severe and personal injuries which are permanent and lasting in nature and the Eli Lilly Defendants failed to adequately warn of said risks.

101. Trulicity, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Eli Lilly Defendants, was defective due to inadequate post-marketing surveillance and/or warnings because, after the Eli Lilly Defendants knew or should have known of the risks of serious side effects, including severe gastrointestinal events (e.g., gastroparesis) and severe digestive events, as well as other severe and permanent health consequences from Trulicity, they failed to provide adequate warnings to users and/or prescribers

of the product, and continued to improperly advertise, market and/or promote their product, Trulicity.

102. The labels for Trulicity were inadequate because it did not warn and/or adequately warn of all possible adverse side effects associated with the use of Trulicity, including the increased risk of gastroparesis and its sequelae.

103. The labels for Trulicity were inadequate because it did not warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including the increased risk of gastroparesis and its sequelae.

104. The labels for Trulicity were inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Trulicity.

105. The labels for Trulicity were inadequate because it did not warn and/or adequately warn of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects.

106. Communications made by the Eli Lilly Defendants to Plaintiff and the prescribing physician(s) were inadequate because the Eli Lilly Defendants failed to warn and/or adequately warn of all possible adverse side effects associated with the use of Trulicity, including the increased risk of gastroparesis and its sequelae.

107. Communications made by the Eli Lilly Defendants to Plaintiff and the prescribing physician(s) were inadequate because the Eli Lilly Defendants failed to warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including the increased risk of gastroparesis and its sequelae.

108. Plaintiff had no way to determine the truth behind the inadequacies of the Eli Lilly Defendants' warnings as identified herein, and Plaintiff's reliance upon the Eli Lilly Defendants' warnings was reasonable.

109. Plaintiff's prescribing physician(s) had no way to determine the truth behind the

inadequacies of the Eli Lilly Defendants' warnings as identified herein, and their reliance upon the Eli Lilly Defendants' warnings was reasonable.

110. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of severe gastrointestinal events (e.g., gastroparesis and gastroenteritis) and gallbladder removal associated with Trulicity, they would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity so as to allow Plaintiff to make an informed decision regarding the use of Trulicity.

111. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including severe gastrointestinal events (e.g., gastroparesis and gastroenteritis) and gallbladder removal, they would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Trulicity so as to allow Plaintiff to make an informed decision regarding the use of Trulicity.

112. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae, which are causally associated with Trulicity, Plaintiff would not have used Trulicity and/or suffered from gastroparesis and its sequelae.

113. Had Plaintiff been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, Plaintiff would not have used Trulicity and/or suffered from gastroparesis and its sequelae.

114. Had Plaintiff been warned of the increased risk of gastroparesis and its sequelae, which are causally associated with Trulicity, Plaintiff would have informed the prescribing physicians that Plaintiff did not want to take Trulicity.

115. Upon information and belief, if Plaintiff had informed the prescribing physician(s) that Plaintiff did not want to take Trulicity because of the aforementioned issues, the prescribing physician(s) would not have prescribed Trulicity.

116. By reason of the foregoing, the Eli Lilly Defendants have become liable to the Plaintiff for the designing, marketing, promoting, distribution and/or selling of an unreasonably dangerous product –Trulicity.

117. The Eli Lilly Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and the Eli Lilly Defendants are therefore liable for the injuries sustained by the Plaintiff in accordance with state law.

118. The Eli Lilly Defendants' inadequate warnings of Trulicity were acts that amount to willful, wanton, and/or reckless conduct by the Eli Lilly Defendants.

119. Said inadequate warnings of Trulicity were a substantial factor in causing Plaintiff's injuries.

120. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

121. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

THIRD CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION AND MAKETING– AGAINST ALL DEFENDANTS)

122. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more

fully set forth herein.

123. At all relevant times, the Eli Lilly Defendants negligently provided Plaintiff, Plaintiff's healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning Trulicity, including, but not limited to, misrepresentations and marketing regarding the safety and known risks of Trulicity.

124. At all relevant times, the Eli Lilly Defendants negligently provided Plaintiff, Plaintiff's healthcare providers, the general medical community, and the public with false, fraudulent, and/or incorrect information or omitted or failed to disclose material information concerning Trulicity, including, but not limited to, misrepresentations and marketing regarding the long term effects of Trulicity.

125. The information distributed by the Eli Lilly Defendants to the public, the medical community, Plaintiff and his healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, and marketing was false and misleading and contained omissions and concealment of truth about the dangers of Trulicity.

126. The Eli Lilly Defendants' conduct had the capacity to deceive and/or its purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's health care providers; to falsely assure them of the quality of Trulicity and induce the public and medical community, including Plaintiff and Plaintiff's healthcare providers to request, recommend, purchase, and prescribe Trulicity.

127. The Eli Lilly Defendants had a duty to accurately and truthfully represent and market to the medical and healthcare community, medical pharmaceutical manufacturers, Plaintiff, Plaintiff's healthcare providers and the public, the known risks of Trulicity, including its propensity to cause malnutrition, cyclical vomiting, gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems

necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, Wernicke's encephalopathy, and death.

128. The Eli Lilly Defendants made continued omissions in the Trulicity labeling, including promoting it as safe and effective while failing to warn of its propensity to cause malnutrition, cyclical vomiting, and gastroparesis, gastroenteritis, intestinal obstruction/blockage, ileus, DVT and associated pulmonary embolism, gallbladder problems necessitating surgery, esophageal injury, bowel injury, intraoperative aspiration, Wernicke's encephalopathy, and death.

129. The Eli Lilly Defendants made additional misrepresentations beyond the product labeling by representing Trulicity as a safe and effective treatment for diabetes with only minimal risks.

130. The Eli Lilly Defendants misrepresented and overstated the benefits of Trulicity to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks to patients.

131. The Eli Lilly Defendants made the misrepresentations alleged herein with the intent to induce consumers, like Plaintiff, to take its diabetes treatment products.

132. In reliance upon the false, deceptive and negligent misrepresentations and omissions and marketing made by the Eli Lilly Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use and prescribe Trulicity, and relied upon the affirmative misrepresentations and/or negligent omissions in doing so.

133. As a direct and proximate result of the foregoing negligent misrepresentations and marketing and conduct with capacity to deceive and/or intention to deceive, Plaintiff suffered serious and ongoing injuries.

134. As a direct and proximate result of the foregoing misrepresentations, marketing, and deceitful intentions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental, and related expenses.

135. The Eli Lilly Defendants knew or should have known that Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true material facts which were intentionally and/or negligently concealed and misrepresented by the Eli Lilly Defendants.

136. Plaintiff and his healthcare providers would not have used or prescribed Ozempic had the true facts not been concealed by the Eli Lilly Defendants.

137. The Eli Lilly Defendants had sole access to many of the material facts concerning the defective nature of Trulicity and its propensity to cause serious and dangerous side effects.

138. At the time Plaintiff was prescribed and administered Trulicity, Plaintiff and Plaintiff's healthcare providers were unaware of the Eli Lilly Defendants' negligent misrepresentations and omissions.

139. The Eli Lilly Defendants failed to exercise ordinary care in making representations concerning Trulicity while it was involved in the manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because Defendants negligently misrepresented Trulicity's high risk of unreasonable and dangerous adverse side effects.

140. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Trulicity Defendants, whereby they concealed and misrepresented facts that were critical to understanding the true and full dangers inherent in the use of the Trulicity.

141. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

FOURTH CAUSE OF ACTION
(STRICT LIABILITY FAILURE TO WARN AGAINST ALL DEFENDANTS)

142. Plaintiff repeats, reiterates, and realleges each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

143. At all relevant times, the Eli Lilly Defendants were responsible for the labeling, packaging, promotion, marketing and sale of the Eli Lilly Defendants' Trulicity that was used by Plaintiff.

144. At all relevant times, the Eli Lilly Defendants were required to warn of Trulicity's potential dangers.

145. At all relevant times, Eli Lilly Defendants' Trulicity was defective or unreasonably dangerous because it lacked adequate warnings.

146. At all relevant times, the Eli Lilly Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the Trulicity that Plaintiff used.

147. Trulicity was expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by the Eli Lilly Defendants.

148. At all relevant times, and at the times Trulicity left the Eli Lilly Defendants' control, the Eli Lilly Defendants knew or should have known that Trulicity was unreasonably dangerous because it did not adequately warn of the risk of gastroparesis and its sequelae, especially when used in the form and manner as provided by the Eli Lilly Defendants.

149. Despite the fact that the Eli Lilly Defendants knew or should have known that Ozempic caused unreasonably dangerous injuries, the Eli Lilly Defendants continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

150. Despite the fact that the Eli Lilly Defendants knew or should have known that Trulicity caused unreasonably dangerous injuries, the Eli Lilly Defendants continued to market Trulicity to prescribing physicians, including Plaintiff's prescribing physician(s), without adequate warnings.

151. The Eli Lilly Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of their failure to provide adequate warnings, as set forth herein.

152. At all relevant times, given their increased safety risks, Trulicity was not fit for the ordinary purposes for which they were intended.

153. At all relevant times, given their increased safety risks, Trulicity did not meet the reasonable expectations of an ordinary consumer, particularly Plaintiff.

154. The Eli Lilly Defendants had a duty to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promotion, advertising, packaging, sale, and/or distribution of Trulicity into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous injuries, such as gastroparesis and its sequelae.

155. At all relevant times, Plaintiff was using Trulicity for the purposes and in a manner normally intended—namely, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

156. Trulicity, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Eli Lilly Defendants was defective due to inadequate warnings or instructions, as the Eli Lilly Defendants knew or should have known that this product created a risk of serious and dangerous injuries, including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, and the Eli Lilly Defendants failed to adequately warn of said risks.

157. Trulicity, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by the Eli Lilly Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after the Eli Lilly Defendants knew or should have known of the risks of serious side effects, including gastroparesis and its sequalae, as well as

other severe and permanent health consequences from Eli Lilly, they failed to provide adequate warnings to users and/or prescribers of these products, and continued to improperly advertise, market and/or promote their products, Eli Lilly.

158. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of gastroparesis and its sequelae.

159. The label for Trulicity was inadequate because it did not warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

160. The label for Trulicity was inadequate because it did not warn and/or adequately warn of all possible adverse side effects concerning the failure and/or malfunction of Trulicity.

161. The label for Trulicity was inadequate because it did not warn and/or adequately warn of the severity and duration of adverse effects, as the warnings given did not accurately reflect the symptoms or severity of the side effects.

162. Communications made by the Eli Lilly Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because the Eli Lilly Defendants failed to warn and/or adequately warn of all possible adverse side effects causally associated with the use of Trulicity, including the increased risk of gastroparesis and its sequelae.

163. Communications made by the Eli Lilly Defendants to Plaintiff and Plaintiff's prescribing physician(s) were inadequate because the Eli Lilly Defendants failed to warn and/or adequately warn that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae.

164. Plaintiff had no way to determine the truth behind the inadequacies of the Eli Lilly Defendants' warnings as identified herein, and Plaintiff's reliance upon the Eli Lilly Defendants' warnings was reasonable.

165. Plaintiff's prescribing physician(s) had no way to determine the truth behind the inadequacies of the Eli Lilly Defendants' warnings as identified herein, and his reliance upon the Eli Lilly Defendants' warnings was reasonable.

166. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risks of gastroparesis and its sequalae, which are causally associated with Eli Lilly, then the prescribing physician(s) would not have prescribed Trulicity, and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity, so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

167. Upon information and belief, had Plaintiff's prescribing physician(s) been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, the prescribing physician would not have prescribed Trulicity, and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of , so as to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

168. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Trulicity, then Plaintiff would not have used Trulicity and/or suffered from gastroparesis and its sequelae.

169. If Plaintiff had been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequalae, then Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

170. If Plaintiff had been warned of the increased risks of gastroparesis and its sequelae, which are causally associated with Trulicity, then Plaintiff would have informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Trulicity.

171. Upon information and belief, if Plaintiff had informed Plaintiff's prescribing physician(s) that Plaintiff did not want to use Trulicity due to the risks of gastroparesis and its

sequelae, or the lack of adequate testing for safety risks, then Plaintiff's prescribing physician(s) would not have prescribed Trulicity.

172. By reason of the foregoing, the Eli Lilly Defendants have become liable to Plaintiff for the designing, marketing, promoting, distribution and/or selling of unreasonably dangerous products, including Trulicity.

173. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and the Eli Lilly Defendants are therefore liable for the injuries sustained by Plaintiff.

174. The Eli Lilly Defendants' inadequate warnings for Trulicity were acts that amount to willful, wanton, and/or reckless conduct by the Eli Lilly Defendants.

175. Said inadequate warnings for the Eli Lilly Defendants' drugs, including Trulicity, were a substantial factor in causing Plaintiff's injuries.

176. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous injuries, including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

177. As a result of the foregoing acts and omissions Plaintiff did incur medical, health, incidental, and related expenses, and requires and/or will require more health care and services. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

FIFTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT AGAINST ALL DEFENDANTS)

178. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

179. At all relevant times, the Eli Lilly Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Trulicity, which was used by Plaintiff as hereinabove described.

180. At all relevant times, the Eli Lilly Defendants knew or should have known that Trulicity had not been adequately and/or sufficiently tested for safety.

181. At all relevant times, the Eli Lilly Defendants knew or should have known that Trulicity was unreasonably dangerous because of the increased risk of gastroparesis and its sequelae, especially when the drug was used in the form and manner as provided by the Eli Lilly Defendants.

182. The Eli Lilly Defendants had a duty to disclose material information about Trulicity to Plaintiff and Plaintiff's prescribing physician(s), namely that Trulicity is causally associated with increased risk of gastroparesis and its sequelae, because the Eli Lilly Defendants have superior knowledge of the drug and its dangerous side effects, this material information is not readily available to Plaintiff or Plaintiff's prescribing physician(s) by reasonable inquiry, and the Eli Lilly Defendants knew or should have known that Plaintiff and Plaintiff's prescribing physician would act on the basis of mistaken knowledge.

183. Nonetheless, the Eli Lilly Defendants consciously and deliberately withheld and concealed from Plaintiff's prescribing physician(s), Plaintiff, the medical and healthcare community, and the general public this material information.

184. Although the Trulicity label lists nausea, vomiting, diarrhea, abdominal pain, and constipation as common adverse reactions reported in Trulicity patients, it does not mention

gastroparesis as a risk of taking Trulicity, nor does it disclose gastroparesis as a chronic condition that can result as a consequence of taking Trulicity.

185. The Eli Lilly Defendants' promotional websites for Trulicity similarly do not disclose that Trulicity is causally associated with increased risk of gastroparesis.

186. The Eli Lilly Defendants' omissions and concealment of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiff's prescribing physician(s), and adult type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume for treatment of type 2 diabetes and/or to promote weight loss.

187. The Eli Lilly Defendants knew or should have known that Plaintiff's prescribing physician(s) would prescribe, and Plaintiff would use Trulicity without the awareness of the risks of serious side effects, including gastroparesis and its sequelae.

188. The Eli Lilly Defendants knew that Plaintiff and Plaintiff's prescribing physicians (s) had no way to determine the truth behind the Eli Lilly Defendants' misrepresentations and concealments surrounding Trulicity, as set forth herein.

189. Upon information and belief, Plaintiffs prescribing physician(s) justifiably relied on the Eli Lilly Defendants' material misrepresentations, including the omissions contained therein, when making the decision to dispense, provide, and prescribe Trulicity.

190. Upon information and belief, had Plaintiff's prescribing physician(s) been warned of the increased risk of gastroparesis causally associated with Trulicity, they would not have prescribed Trulicity and/or would have provided Plaintiff with adequate information regarding the increased risk of gastroparesis causally associated with Trulicity to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

191. Upon information and belief, had Plaintiff's prescribing physician(s) been told that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis

and its sequelae, they would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Trulicity to allow Plaintiff to make an informed decision regarding Plaintiff's use of Trulicity.

192. Plaintiff justifiably relied on the Eli Lilly Defendants' material misrepresentations, including the omissions contained therein, when making the decision to purchase and/or consume Trulicity.

193. Had Plaintiff been informed of the increased risks causally associated with Trulicity, Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

194. The Eli Lilly Defendants' fraudulent concealments were a substantial factor in causing Plaintiff's injuries.

195. As a direct and proximate result of the above stated omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

196. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SIXTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION-AGAINST ALL DEFENDANTS)

197. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

198. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Trulicity, which was used by Plaintiff as hereinabove described.

199. At all relevant times, Defendants knew or should have known that Trulicity had not been adequately and/or sufficiently tested for safety.

200. At all relevant times, Defendants knew or should have known of the serious side effects of Trulicity, including gastroparesis and its sequelae.

201. At all relevant times, Defendants knew or should have known that Trulicity was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or promote weight loss, given its increased risk of gastroparesis.

202. Nonetheless, Defendants made material misrepresentations to Plaintiff, Plaintiffs prescribing physician(s), the medical and healthcare community at large, and the general public regarding the safety and/or efficacy of Trulicity.

203. Defendants represented affirmatively and by omission on television advertisements and on the label of Trulicity that Trulicity was a safe and effective drug for treatment of adults with Type 2 diabetes, despite being aware of increased risks of gastroparesis and its sequelae causally associated with using Trulicity.

204. Defendants were aware or should have been aware that its representations were false or misleading and knew that they were concealing and/or omitting material information from Plaintiff, Plaintiffs prescribing physician(s), the medical and healthcare community, and the general public.

205. Defendants' misrepresentations of material facts were made purposefully, willfully, wantonly, and/or recklessly in order to mislead and induce medical and healthcare providers, such as Plaintiffs prescribing physician(s), and adult Type 2 diabetes patients, such as Plaintiff, to dispense, provide, prescribe, accept, purchase, and/or consume Trulicity for treatment of Type 2

Diabetes.

206. Upon information and belief that Plaintiffs prescribing physician(s) had no way to determine the truth behind Defendants' false and/or misleading statements, concealments and omissions surrounding Trulicity, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiffs prescribing physician(s) had no way to know were omitted.

207. Upon information and belief that Plaintiffs prescribing physician(s) justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to prescribe Trulicity to Plaintiff.

208. Upon information and belief, had Plaintiffs prescribing physician(s) been informed of the increased risk of gastroparesis causally associated with Trulicity, Plaintiffs prescribing physician(s) would not have prescribed Trulicity and/or would have provided Plaintiff with adequate information regarding safety of Trulicity to allow Plaintiff to make an informed decision regarding Plaintiffs use of Trulicity.

209. Upon information and belief, had Plaintiffs prescribing physician(s) been told that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis and its sequelae, they would not have prescribed Trulicity and/or would have provided Plaintiff with adequate warnings regarding the lack of sufficient and/or adequate testing of Trulicity so that Plaintiff can make an informed decision regarding Plaintiffs use of Trulicity.

210. Plaintiff had no way to determine the truth behind Defendant's false and/or misleading statements, concealments and omissions surrounding Trulicity, and reasonably relied on false and/or misleading facts and information disseminated by Defendants, which included Defendants' omissions of material facts in which Plaintiff had no way to know were omitted.

211. Plaintiff justifiably relied on Defendants' material misrepresentations, including the omissions contained therein, when making the decision to accept, purchase and/or consume

Trulicity.

212. Had Plaintiff been told of the increased risk of gastroparesis and its sequelae causally associated with Trulicity, Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

213. Had Plaintiff been told of the lack of sufficient and/or appropriate testing of Trulicity for safety risks, including gastroparesis and its sequelae, Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

214. As a direct and proximate result of the above stated false representations and/or omissions as described herein, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

215. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

SEVENTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY-AGAINST ALL DEFENDANTS)

216. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

217. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have acquired the Defendants who designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed

Trulicity, which was used by Plaintiff as hereinabove described.

218. At all relevant times, Defendants expressly warranted to Plaintiff and Plaintiffs prescribing physician(s) that Trulicity was safe to treat 2 diabetes, reduce cardiovascular risk, and promote weight loss and assure them it did not carry an increased risk of gastrointestinal complications, including, but not limited to, gastroparesis.

219. The aforementioned express warranties were made to Plaintiff and Plaintiffs prescribing physician(s) by way of Trulicity's labels, website, advertisements, promotional materials, and through other statements.

220. As a result of Defendants' express warranties, Plaintiffs prescribing physician(s) was induced to, and did, prescribe Trulicity to Plaintiff, and Plaintiff was induced to, and did, use Trulicity.

221. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Trulicity based upon their express warranties.

222. At all relevant times, Defendants reasonably anticipated and expected that prescribing physicians, such as Plaintiffs prescribing physician(s), would recommend, prescribe and/or dispense Trulicity based upon their express warranties.

223. At all relevant times, Defendants knew or should have known that Trulicity was unreasonably dangerous because of its increased risk of gastroparesis and its sequelae, especially when the drug was used in the form and manner as provided by Defendants.

224. At all relevant times, Defendants knew or should have known that Trulicity had not been sufficiently and/or adequately tested for safety.

225. The unreasonably dangerous characteristics of Trulicity were beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drug's characteristics.

226. The unreasonably dangerous characteristics of Trulicity were beyond that which would be contemplated by Plaintiffs prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

227. At the time Trulicity left Defendants' control, Trulicity did not conform to Defendants' express warranties because Trulicity was not safe to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk in patients with type 2 diabetes, or to promote weight loss, in that it was causally associated with increased risks of gastroparesis and its sequelae.

228. The express warranties made by Defendants regarding the safety of Trulicity were made with the intent to induce Plaintiff to use the product and/or Plaintiff prescribing physician(s) to prescribe the product.

229. Defendants knew and/or should have known that by making the express warranties to Plaintiff and/or Plaintiffs prescribing physician(s), it would be the natural tendency of Plaintiff to use Trulicity and/or the natural tendency of Plaintiffs prescribing physician(s) to prescribe Trulicity.

230. Plaintiff and Plaintiffs prescribing physician(s), as well as members of the medical community, relied on the express warranties of Defendants identified herein.

231. Had Defendants not made these express warranties, Plaintiff would not have used Trulicity and/or, upon information and belief, Plaintiffs prescribing physician(s) would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity so as to allow Plaintiff to make an informed decision regarding Plaintiffs use of Trulicity.

232. Had Plaintiff been warned of the increased risk of gastroparesis causally associated with Trulicity, Plaintiff would not have used Trulicity and and/or suffered from gastroparesis and its sequelae.

233. Had Plaintiff been warned that Trulicity had not been sufficiently and/or adequately tested for safety risks, including gastroparesis, Plaintiff would not have used Trulicity and/or suffered gastroparesis and its sequelae.

234. Accordingly, Defendants are liable as a result of their breach of express warranties to Plaintiff.

235. Defendants' breach of express warranty was a substantial factor in causing Plaintiffs injuries.

236. Plaintiffs injuries and damages arose from a reasonably anticipated use of the products by Plaintiff.

237. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, as well as other severe and personal injuries which are permanent and lasting in nature, including physical pain, mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

238. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require more constant and continuous medical monitoring and treatment than prior to Plaintiffs use of Defendants' Trulicity drug.

239. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

EIGTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY-AGAINST ALL DEFENDANTS)

240. Plaintiff repeats, reiterates, and realleges each and every allegation of this

Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

241. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Trulicity drug used by Plaintiff.

242. Trulicity was expected to and did reach the usual consumers, handlers, and persons encountering said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

243. At all relevant times, Defendants impliedly warranted to Plaintiff, Plaintiffs prescribing physician(s), and the medical community that Trulicity was of merchantable quality and safe and fit for its ordinary purpose.

244. At all relevant times, Defendants knew or should have known that Trulicity was unreasonably dangerous because of its increased risk of gastroparesis and its sequelae, especially when the drug was used in the form and manner as provided by Defendants.

245. At all relevant times, Defendants knew or should have known that Trulicity had not been sufficiently and/or adequately tested for safety.

246. At the time Trulicity left Defendants' control, Trulicity did not confirm to Defendants' implied warranties and was unfit for its ordinary purpose because Defendants failed to provide adequate warnings of the drug's causal association with increased risk of gastroparesis and its sequelae.

247. At all relevant times, Defendants reasonably anticipated and expected that prescribing physician(s), such as Plaintiffs prescribing physician(s), would recommend, prescribe and/or dispense Trulicity for use by their patients to improve glycemic control in adults with type 2 diabetes, reduce cardiovascular risk, and/or to promote weight loss.

248. At all relevant times, Defendants reasonably anticipated and expected that individuals, such as Plaintiff, would use and/or consume Trulicity for its ordinary purpose.

249. Despite the fact that Defendants knew or should have known that Trulicity causes unreasonably dangerous injuries, such as gastroparesis and its sequelae, Defendants continued to market, distribute, and/or sell Trulicity to consumers, including Plaintiff, without adequate warnings.

250. The unreasonably dangerous characteristics of Trulicity was beyond that which would be contemplated by the ordinary user, such as Plaintiff, with the ordinary knowledge common to the public as to the drugs' characteristics.

251. The unreasonably dangerous characteristics of Trulicity was beyond that which would be contemplated by Plaintiffs prescribing physician(s), with the ordinary knowledge common to prescribing physician as to the drugs' characteristics.

252. Plaintiff reasonably relied on Defendants' implied warranty of merchantability relating to Trulicity's safety and efficacy.

253. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Trulicity was of merchantable quality and safe and fit for its intended use.

254. Upon information and belief Plaintiffs prescribing physician(s) relied on Defendants' implied warranty of merchantability and fitness for the ordinary use and purpose relating to Trulicity.

255. Upon information and belief Plaintiffs prescribing physician(s), reasonably relied upon the skill and judgment of Defendants as to whether Trulicity was of merchantable quality and safe and fit for its intended use.

256. Had Defendants not made these implied warranties, Plaintiff would not have used Trulicity and/or, upon information and belief, Plaintiffs prescribing physician(s) would not have prescribed Trulicity, and/or would have altered their prescribing practices and/or would have provided Plaintiff with adequate warnings regarding the dangers of Trulicity to allow Plaintiff to make an informed decision regarding Plaintiffs use of Trulicity.

257. Defendants herein breached the aforementioned implied warranty of merchantability because the drug Trulicity was not fit for its intended purposes.

258. Defendants' breaches of the implied warranty of merchantability were a substantial factor in causing Plaintiffs injuries.

259. As a result of the foregoing breaches, Plaintiff was caused to suffer serious and dangerous injuries including gastroparesis and its sequelae, which resulted in other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

260. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will require future medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: February 6, 2025.

By: */s/ T. Roe Frazer II*

T. Roe Frazer II (#35785)
FRAZER PLC
30 Burton Hills Blvd, Ste 450
Nashville, TN 37215
(615) 647-6464 (Telephone)
(615) 307-4902 (Fax)
roe@frazer.law
Attorney for Plaintiff